BioSpectrum the business of Bio & Health Sciences

Partnering CROs

11 March 2008 | News

Image not found or type unknown

Partnering CROs

Utkarsh Palnitkar, Partner, Transaction Advisory Services, Ernst & Young

More and more businesses around the world are turning to strategic relationships--alliances, joint ventures (JVs), outsourcing arrangements, networks and other partnerships--as a way to gain a competitive edge in today's global business environment. Over the last two decades, pharmaceutical companies have become increasingly dependent on using third parties to conduct their operations. This has resulted in the emergence of the 'networked pharma' model. Alliance management has been identified as the key with enhanced focus on licensing (both in and out), outsourcing agreements and collaborations spanning the value chain. In the most extreme form of the model, core competencies, such as strategic planning, are retained in-house, while the rest of the required functions, such as manufacturing, sales and marketing, and R&D, are carried out by a network of partners through a combination of outsourcing deals, collaborations and in-licensing deals.

Recent trends

The extensive research breakthroughs in biology make it tough even today for the largest pharmaceutical giants to put together all the necessary capabilities. In addition, the technology-intensive nature of the pharmaceutical industry means that complex organizational issues will govern alliance formation. Vertical integration, in particular, faces severe challenges, so much so that collaborative ventures are likely to become the dominant institutional arrangement of the industry. Such arrangements permit companies with widely differing competencies and resources to depend on each other's strengths and thus build a new business model of virtual integration. As the company augments its experience and as collaborative practices become institutionalized, Returns on Investment (RoI) in alliances are expected to increase.

An alternative trend being noted is the evolution of the CRO industry away from modularity (i.e., providing development outsourcing only, as a stand-alone business) towards re-integration. CROs such as Quintiles (via NovaQuest) are becoming comparable to pharmaceutical companies and less like third party vendors. Re-integration occurs when outsourced functions become commoditized, as the drug development function has become. Large CRO players need new avenues of business growth; they comprehend that integration of functional expertise and processes, like in a major pharma, creates efficiencies and competitive barriers that can perhaps lead to new growth.

Changing partnering landscape in India

In India, a silent shift from service-based to a partnership-led model has taken place over the past few months. The shift was a result of the operating environs of the industry that underwent a dramatic transformation. Typical partnership models followed by CROs are service provider/licensor, strategic collaborations, preferred partner or shareholder arrangement/equity stake. Equity stake ensures control over the Intellectual Property (IP), quality communication and trust owing to long-term relationships. This leads to a win-win situation for both the vendor and the sponsor.

The partnership between The Institute of Microbial Technology (IMTECH) and Nostrum Pharma highlights a partnership model based on licenses. IMTECH, Chandigarh, a Council of Scientific and Industrial Research (CSIR) laboratory and Nostrum Pharmaceutical Inc., USA, have entered into a technology licensing agreement whereby the latter will obtain worldwide licensing rights from IMTECH to carry out clinical development and commercialization of a novel clot busting therapeutic protein.

Siro and Covance illustrate the preferred partnership model. Siro, the preferred partner, has the first right of refusal for any clinical trial work outsourced by Covance to India. The collaboration would entail supporting and enhancing the research efforts of the domestic and international biopharma companies.

The GSK-Ranbaxy drug discovery deal is a case in point of strategic collaboration. Ranbaxy would advance GSK's leads beyond candidate selection to completion of clinical proof of concept. GSK will conduct clinical development to commercialization and would be responsible for bringing the molecule to market.

Parexelâ€“Synchron and Ethica Clinical Researchâ€“Matrix alliances are good examples of the fourth partnership model that pertains to equity stake. Parexel had purchased a majority stake in a newly formed entity called Parexel International Synchron Private Ltd that would be handling Synchron's clinical trial business operations. Parexel also acquired a minority equity interest in the clinical pharmacology business of Synchron Research in Ahmedabad, India.

Ethica Clinical Research and Matrix formed a new company Ethicamatrix CRO ("Ethicamatrix") for providing contract research services in India on behalf of North American, European and Indian pharmaceutical and biotechnology companies. The initial focus would be on services that include study monitoring, data management, and investigator training.

During the past few years, a fifth option has evolved which takes care of the many drawbacks of the previous partnership models. This new option, the formation of a development partnership, is collaboration between two companies: one with a promising new product candidate and another with an established development infrastructure. In this type, each company has an equity stake in the product's success in a development program usually co-managed by both. On a similar vein, program expenditures are shared, which help to reduce expenses and minimize risk.

In today's world, alliances are both risky and necessary. Alliances are here to stay and are the wave of the future in the bio-pharmaceutical industry. Given the fast moving technological frontier and the vast resources needed to thrive in this industry, developing and implementing sound alliance strategies have become compulsory. The good news is that Indian pharmaceutical companies have started to re-invent themselves in response to market challenges, and they look very different than they did just five years ago. To succeed, companies need to get ahead of the dynamics that are rebalancing the market. This requires a greater reliance on scenario-based planning, a sharper focus on realizing productivity gains from sales and marketing expenditures, and continued investments in basic drug discovery and research.

Service and Partnership Models

Contract Services (Services-based)	Strategic and Collaborative Alliances (Partnership-led)
Threat from generics	Alignment of IP regime to global standards
Decrease in R&D productivity	Global regulatory climate
Emphasis on cost containment	Favorable Policy framework and increased investor interest
Favorable economics of manpower and infrastructure in India	Shift towards basic innovation
Relevant capacity building in India	Companies building global capacities